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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,711	12/12/2001	Jennifer June Brown	ENZ-57 (CIP) (C)	4374

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EXAMINER	
FALK, ANNE MARIE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/042,711	BROWN ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *34-74* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed August 10, 2005 has been entered. Claims 1-33 were cancelled and Claims 34-74 were newly added.

Accordingly, Claims 34-74 are pending in the instant application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 34-37 and 52-57, drawn to a method of screening a therapeutic drug using a lower primate infected with a human viral pathogen (*in vivo* testing of a compound), classified in class 424, subclass 9.2.

II. Claim 38, drawn to a method of screening a therapeutic drug using cells, tissues, or organs infected *in vitro* with a human viral pathogen (*in vitro* testing of a compound), classified in class 435, subclass 5.

III. Claims 39-41, 43, 49-51, 58-63, and 69-74, drawn to a method for developing a therapeutic procedure in a model animal system (*in vivo* testing of a procedure), classified in class 424, subclass 9.1.

IV. Claim 42, drawn to a method for developing a therapeutic procedure, wherein the method involves using cells, tissues or organs from a lower primate (*in vitro* testing of a procedure), classified in class 435, subclass 1.1.

V. Claims 44-48 and 64-68, drawn to a composition comprising a therapeutic drug effective in alleviating clinical manifestations of a disease caused by a human viral pathogen, classified in class unspecified, subclass unspecified.

Although Claims 46-48 recite "the method of claim 44" they are assumed to be directed to the **composition** of Claim 44, since Claim 44 is not directed to a method. Therefore, Claims 46-48 are included in Group V, directed to the composition.

Likewise, Claim 65 is assumed to be directed to the **composition** of Claim 64, despite recitation of "the method of claim 64," since Claim 64 is directed to a composition. Therefore, Claim 65 is included in Group V, directed to the composition.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because the inventions are drawn to mutually exclusive and independent methods for screening a potential therapeutic drug. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods require the use of different starting materials and different modes of operation. The method of the invention of Group I requires administration of a potential therapeutic drug to an infected animal, whereas the method of the invention of Group II requires infecting a cell, tissue or organ *in vitro* with a human viral pathogen and contacting the cell, tissue or organ *in vitro* with a potential therapeutic drug. The protocols for *in vivo* drug screening are materially different and separate from the protocols for *in vitro* drug screening. The methods as claimed utilize different starting materials, have different method steps, and produce different effects. Thus, the method of the invention of Group I is patentably distinct from the method of the invention of Group II.

Furthermore, the distinct steps and starting materials require separate and distinct searches. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I and II together in a single patent application.

Each of the inventions of Groups I and II requires consideration of separate issues relating to assessment of novelty, obviousness, utility, written description, and enablement. For example, the invention of Group I requires consideration of issues relating to the *in vivo* evaluation of a potential therapeutic effect which is not required for examination of the invention of Group II. Furthermore, the searches for the inventions of Groups I and II are not coextensive. For example, a search for the animal to be used in the method of the invention of Group I would not necessarily identify art teaching assays for cells, tissues or organs in relation to *in vitro* drug screening as required in the method of the invention of Group II. Additional searching would be required to cover the method of the invention of Group II and assays appropriate for use in determining therapeutic potential in the *in vitro* screening method of the invention of Group II. Thus, search and examination of both inventions in a single patent application constitutes a serious burden on the Office.

Inventions I and III are patentably distinct because the inventions are drawn to mutually exclusive and independent methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods require the use of different starting materials, have different method steps, and different modes of operation. The method of the invention of Group I requires administration of a potential therapeutic drug to an infected animal, whereas the method of the invention of Group III requires carrying out a therapeutic protocol on an infected animal. The therapeutic protocol would have its own method steps, which are not defined in the claimed method, and which would not be steps common to the method of the invention of Group I. A potential therapeutic procedure would necessarily produce a different outcome from a potential therapeutic drug. The methods as claimed utilize different starting materials, have different method steps, and produce different effects. Thus, the method of the invention of Group I is patentably distinct from the method of the invention of Group III.

Inventions I and IV are patentably distinct because the inventions are drawn to mutually exclusive and independent methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods require the use of different starting materials, have different method steps, and different modes of operation. The method of the invention of Group I requires administration of a potential therapeutic drug to an infected animal, whereas the method of the invention of Group IV requires infecting a cell, tissue or organ *in vitro* with a human viral pathogen and carrying out a therapeutic protocol on the cell, tissue or organ. The therapeutic protocol would have its own method steps, which are not defined in the claimed method, and which would not be steps common to the method of the invention of Group I. The protocols for *in vivo* drug screening are materially different and separate from the protocols for *in vitro* procedure screening. Furthermore, the evaluating step for an *in vivo* drug screening method would be materially different from the evaluating step for an *in vitro* procedure screening method. An in vivo drug screening method would necessarily produce different effects and a different outcome from an in vitro procedure screening method. The methods as claimed utilize different starting materials, have different method steps, and produce different effects. Thus, the method of the invention of Group I is patentably distinct from the method of the invention of Group IV.

Inventions I and V are patentably distinct because the inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The claims of Group V, directed to a composition identified by a drug screening method to have a therapeutic effect, are reach-through claims. In the instant case, the composition of the invention of Group V is not required for the method of the invention of Group I, which is directed to screening all types of compounds, including those that show no therapeutic effect. As such, the composition of the invention of

Group V is not required for practice of the method of the invention of Group I. Thus, the composition of the invention of Group V is patentably distinct from the method of the invention of Group I.

Inventions II and III are patentably distinct because the inventions are drawn to mutually exclusive and independent methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods require the use of different starting materials, have different method steps, and different modes of operation. The method of the invention of Group II requires infecting cells, tissues, or organs with a human viral pathogen and contacting the cells, tissues, or organs with a potential therapeutic drug, whereas the method of the invention of Group III requires carrying out a therapeutic protocol on an infected animal. The therapeutic protocol would have its own method steps, which are not defined in the claimed method, and which would not be steps common to the method of the invention of Group II. A potential therapeutic drug would necessarily produce different effects *in vitro* from a therapeutic procedure carried out *in vivo* using an infected animal. The methods as claimed utilize different starting materials, have different method steps, and produce different effects. Thus, the method of the invention of Group II is patentably distinct from the method of the invention of Group III.

Inventions II and IV are patentably distinct because the inventions are drawn to mutually exclusive and independent methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods require the use of different starting materials, have different method steps, and different modes of operation. The method of the invention of Group II requires infecting cells, tissues, or organs with a human viral pathogen and contacting the cells, tissues, or organs with a potential therapeutic drug, whereas the method of the

invention of Group IV requires infecting a cell, tissue or organ *in vitro* with a human viral pathogen and carrying out a therapeutic protocol on the cell, tissue or organ. The therapeutic protocol would have its own method steps, which are not defined in the claimed method, and which would not be steps common to the method of the invention of Group II. The protocols for *in vitro* drug screening are materially different and separate from the protocols for *in vitro* procedure screening. As such, the methods as claimed utilize different starting materials, have different method steps, and produce different effects. Thus, the method of the invention of Group II is patentably distinct from the method of the invention of Group IV.

Inventions II and V are patentably distinct because the inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The claims of Group V, directed to a composition identified by a drug screening method to have a therapeutic effect, are reach-through claims. In the instant case, the composition of the invention of Group V is not required for the method of the invention of Group II, which is directed to screening all types of compounds, including those that show no therapeutic effect. As such, the composition of the invention of Group V is not required for practice of the method of the invention of Group II. Thus, the composition of the invention of Group V is patentably distinct from the method of the invention of Group II.

Inventions III and IV are patentably distinct because the inventions are drawn to mutually exclusive and independent methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods require the use of different starting materials, have different method steps, and different modes of operation. The method of the invention of Group III requires carrying out a potential therapeutic protocol on an infected animal,

whereas the method of the invention of Group IV requires infecting a cell, tissue or organ *in vitro* with a human viral pathogen and carrying out a therapeutic protocol on the cell, tissue or organ. The therapeutic protocol would have its own method steps, which are not defined in the claimed method, and which would not necessarily be steps common to the method of the invention of Group III. The protocols for *in vivo* testing of a procedure are materially different and separate from the protocols for *in vitro* testing of a procedure. Furthermore, the evaluating step for an *in vivo* procedure screening method would be materially different from the evaluating step for an *in vitro* procedure screening method. An *in vivo* procedure screening method would necessarily produce different effects and a different outcome from an *in vitro* procedure screening method. The methods as claimed utilize different starting materials, have different method steps, and produce different effects. Thus, the method of the invention of Group III is patentably distinct from the method of the invention of Group IV.

Inventions III and V are patentably distinct because the inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The claims of Group V, directed to a composition identified by a drug screening method to have a therapeutic effect, are reach-through claims. In the instant case, the composition of the invention of Group V is not required for the method of the invention of Group III, which is directed to testing a procedure. As such, the composition of the invention of Group V is not required for practice of the method of the invention of Group III. Thus, the composition of the invention of Group V is patentably distinct from the method of the invention of Group III.

Inventions IV and V are patentably distinct because the inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The

claims of Group V, directed to a composition identified by a drug screening method to have a therapeutic effect, are reach-through claims. In the instant case, the composition of the invention of Group V is not required for the method of the invention of Group IV, which is directed to *in vitro* testing of a procedure. As such, the composition of the invention of Group V is not required for practice of the method of the invention of Group IV. Thus, the composition of the invention of Group V is patentably distinct from the method of the invention of Group IV.

Each of the inventions of Groups I-V requires consideration of separate issues relating to assessment of novelty, obviousness, utility, written description, and enablement. For example, the invention of Group I requires consideration of issues relating to the enablement of a lower primate for susceptibility to infection with a human viral pathogen which is not required for examination of the invention of Group V. Furthermore, the searches for the inventions of Groups I-V are not coextensive. For example, a search for a lower primate susceptible to infection with a human viral pathogen would not necessarily identify art on a potential therapeutic procedure or the testing of a potential therapeutic procedure. Additional searching would be required to cover the *in vivo* procedure screening methods of the invention of Group III. Thus, search and examination of all 5 inventions in a single patent application constitutes a serious burden on the Office.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER